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10/579,203	02/27/2007	Christian J. Strasburger	2905493-000003	6904

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KENING LI
PINSENT MASONS LLP
c/o FOUNTAIN LAW GROUP, INC
18201 Von Karman Avenue, Suite 960
Irvine, CA 92612

EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,203	STRASBURGER ET AL.	
	Examiner	Art Unit	
	STEPHEN GUCKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-65* is/are pending in the application.

4a) Of the above claim(s) *62-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I-VIII, claim(s) 50, 52, and 62 drawn to an antibody or a specific antigen-binding fragment thereof (or a fusion protein) that binds specifically to one or both of a leptin receptor and a leptin-binding protein and reduces interaction of the leptin receptor or of the leptin-binding protein with its ligand, each Group corresponding to one SEQ ID NO., i.e. Group I = SEQ ID NO:1, Group II = SEQ ID NO:2, ...Group VIII = SEQ ID NO:8.

Group IX, claim(s) 63, drawn to a method for quantitative determination of a ligand of a leptin binding protein or of a leptin receptor in a sample.

Group X, claim(s) 64-65, drawn to a method for treating a disease or a condition due to excessive leptin level in a patient in need thereof.

2. Claims 43-49, 51, and 53-61 link(s) inventions I through VIII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 43-49, 51, and 53-61. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a special technical feature by definition must be a contribution over the prior art. However, Sierra-Honigmann (WO 99/59614, "Sierra-Honigmann") disclose antibodies that prevent the formation of the leptin/leptin receptor complex, as was indicated in the international search report for the instant application (page 24, lines 13-18). Therefore, an antibody that binds specifically to a leptin receptor and reduces interaction of the leptin receptor with its ligand is not a contribution over the prior art, anticipates many of the linking claims linking Groups I-VIII, and as a result Groups I-X lack a special technical feature.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper

restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. During a telephone conversation with Kening Li on 7/24/09, a provisional election was made with traverse to prosecute the invention of Group VI (SEQ ID NO:6), claims 43-61 (linking claims included). Affirmation of this election must be made by applicant in replying to this Office action. Claims 62-65 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Page 15 of the specification indicates that the monoclonal antibody ZMC2 has been deposited according to the stipulations of the Budapest treaty. However, a statement is required that all restrictions imposed by the

depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent is required. See MPEP 2410.01.

Claim 52 as drawn to SEQ ID NO:6 is rejected because SEQ ID NO:6 is the histidine labeled heavy chain of a leptin binding antibody. SEQ ID NO:6 contains only 3 CDRs for binding of the leptin. However, 6 CDRs (heavy chain combined with light chain) are required to produce the desired biological activity. The grounds of this rejection may be obviated by amending the claim to recite an appropriate light chain (such as SEQ ID NO:1) that combined with the heavy chain would produce the desired activity. See the instant specification at pages 13-15 for possible descriptive support for amending claim 52. The Examiner is also receptive to being contacted by Applicant for assistance in drafting appropriate claims in this regard.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 43-49, 51, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Sierra-Honigmann. Sierra-Honigmann teaches polyclonal, monoclonal, humanized, and chimeric antibodies and fragments thereof (page 20) that reduce the interaction of the leptin receptor with its ligand leptin (page 24) by binding to the extracellular domain of the leptin receptor (page 39). The antibodies can be single-chain (ScFv) or Fab fragments (page 26).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 55-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (US 7,446,183, "Ross") in view of Sierra-Honigmann. Ross teaches bispecific fusion proteins comprising a ligand such as leptin (column 5, line 49) and a binding agent comprising at least part of the cognate receptor for leptin (column 5, lines 57-59) in order to produce a specific receptor antagonist which is a chimera of the ligand and its cognate receptor (column 5, line 66 to column 6, line 6). The fusion protein is linked by 5-30 glycine residues (column 6, lines 38-40). Ross does not teach a bispecific fusion protein of leptin and an antibody binding the leptin receptor as a specific receptor antagonist. Sierra-Honigmann teaches an antibody binding the leptin receptor as a leptin antagonist as set forth above. It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the leptin

receptor part of the fusion protein with the leptin receptor binding antibody part of Sierra-Honigmann because either part produces the same function of inhibiting the biological action of leptin. The number of choices for this part is very finite – either the free leptin can be bound by a "faux" receptor (of the fusion protein) and have its function inhibited (because the leptin is not free to activate its "genuine" cell surface receptor), or the cell surface leptin receptor can be bound by a blocking antibody as taught by Sierra-Honigmann and not be free to bind leptin and be biologically activated. Because of the finite number of choices to produce the same biological function of leptin antagonism involving the inhibition of binding interaction of only (a) leptin or (b) leptin receptor with each other (a binding to b), the substitution of the active feature of one reference for the other is obvious. Essentially, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention because the nexus between the references makes the substitution of a known functionally similar binding domain from a finite list for a known similar purpose (inhibit leptin binding to its true cell surface receptor) in order to produce a known similar result (inhibit leptin biological activity) with a reasonable expectation of success is *prima facie* obvious. See *KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (U.S. 2007).*

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

August 19, 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649